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Application Number 10/006 500 0 and 400 700

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		First Named Inventor		Kazuo IWAI	
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ENCLOSURES (Check all that apply)					
Fee Transmittal Form	Drawing(s)			After Allowance Communication to TC	
Fee Attached	Licensing-related Papers			Appeal Communication to Board of Appeals and Interferences	
Amendment/Reply	Petition			Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)	
After Final	Petition to Convert to a Provisional Application			Proprietary Information	
Affidavits/declaration(s)	Affidavits/declaration(s) Power of Attorney, Revocation Change of Correspondence Are			Status Letter	
Extension of Time Request	ktension of Time Request			X Other Enclosure(s) (please Identify below):	
Express Abandonment Request	Request for I	Refund		Reply to Notification of Non- Compliant Brief	
Information Disclosure Statement CD, Number of		of CD(s)		Substitute Brief on Appeal	
Certified Copy of Priority Document(s)		ape Table on	CD		
Reply to Missing Parts/ Incomplete Application	Remarks				
Reply to Missing Parts under 37 CFR 1.52 or 1.53					
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT					
BIRCH, STEWART, KOLASCH & BIRCH, LLP					
Signature & Many A					
Printed name Gerald M. Murphy, or	Geraid yn. Wurpny, yr. (7				
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IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:

Kazuo IWAI

Conf.: 3472

Appl. No.:

10/006,569

Group: 3643

Filed:

December 10, 2001

Examiner:

Timothy Cole

For:

METHOD OF STERLIZING POULTRY MEAT

REPLY TO NOTIFICATION OF NON-COMPLIANT BRIEF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

August 20, 2007

Sir:

In reply to the Notification of Non-Compliant Brief dated July 18, 2007, appellants submit herewith a substitute Appeal Brief which addresses the informalities noted by the Examiner at paragraph 10 of the Notice.

More specifically, the Summary (Section V) is revised to more specifically discuss the support for the independent claims. The headings for Section VII and the claim and evidence appendices are corrected.

Appellants accordingly request that the Brief be submitted to the Honorable Board of Appeals for further consideration.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

P.O. Box 147

Falls Church, VA 22040-0747

(703) 205-8000

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Kazuo IWAI Conf.: 3472

Appl. No.: 10/006,569 Group: 3643

Filed: December 10, 2001 Examiner: Price

For: METHOD OF STERILIZING POULTRY MEAT

SUBSTITUTE BRIEF ON APPEAL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

August 20, 2007

Sir:

Appellant hereby appeals the Final Rejection of June 14, 2005, finally rejecting claims 11-22 and 24-27.

I. Real Parties in Interest

The real parties in interest in this appeal are JCS, Inc. and Osaka Organic Chemical, Ltd.

II. Related Appeals and Interferences

There are no related appeals or interferences at this time.

III. Status of Claims

The status of the claims is as follows:

Claims 1-10 and 23

Cancelled

Claims 11-22 and 24-27: Rejected and under appeal

IV. Status of Amendments

No amendments under 37 CFR 1.116 have been filed.

V. Summary of Claimed Subject Matter

The present invention is directed to a method of sterilizing poultry meat. The present invention involves subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution in poultry processing for production of poultry meat as particularly described at pages 7-12 of the specification. The contact treatment is carried out in one or more steps comprising an evisceration step, a chilling step or a wrapping step. It has been demonstrated by appellant that the use of hinokitol enables poultry meat to be sterilized without disadvantageous effect upon odor or appearance of the poultry meat.

a. Independent Claim 11 and Corresponding Dependent Claims 13-16, 26 and 27

Independent claim 11 is directed to a method of sterilizing poultry meat comprising the step of subjecting poultry meat to a contact treatment with an aqueous solution consisting essentially of hinokitiol and water (page 7, lines 19-25 and page 8, lines 1-16) in poultry processing for production of poultry meat, wherein the contact treatment is carried out in

one or more steps (page 8, lines 22-25, page 9, lines 1-2) selected from the group consisting of an evisceration step, a chilling step and a wrapping step (page 9, lines 13-18), wherein the hinokitiol aqueous solution-contacted poultry meat is wrapped (page 12, lines 1-2).

Dependent claim 12 provides that the contact treatment is carried out either between the evisceration step and the chilling step, or between the chilling step and the wrapping step.

Dependent claim 13 provides for a hinokitiol solution concentration of from 1 to 50,000 ppm.

Dependent claim 14 states that the hinokitiol solution pH is from 4 to 11.

Dependent claim 15 states that the contacting temperature is from 0° to 70°C.

Dependent claim 16 states that the contact occurs by means of coating, spraying, rubbing or immersion.

Dependent claim 26 provides for the presence of a surfactant in the hinokitiol solution.

Dependent claim 27 provides for the additional presence of a plant extract in the hinokitiol solution.

b. Independent Claim 17 and Corresponding Dependent Claims 18-22

Independent claim 17 is directed to a method of sterilizing poultry meat comprising the step of subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution consisting essentially of hinokitiol and water (page 7, lines 19-26, page 8, lines 16) during poultry processing for production of poultry meat, wherein the contact treatment is carried out in one or more intervals between consecutive two steps (page 8, lines 22-25) selected from the group consisting of (1) between an evisceration step and a chilling step (page 10, lines 17-22)

and (2) between a chilling step and a wrapping step (page 10, lines 23-24), wherein the hinokitiol aqueous solution-contacted poultry meat is wrapped (page 12, lines 1-2). The embodiment of claim 17 is described at pages 10-12 of the specification.

Dependent claim 18 states that the contacting step is carried out at a chilling step.

Dependent claim 19 provides for a hinokitiol solution concentration of from 1 to 50,000 ppm.

Dependent claim 20 states that the hinokitiol solution pH is from 4 to 11.

Dependent claim 21 states that the contacting temperature is from 0° to 70°C.

Dependent claim 22 states that the contact occurs by means of coating, spraying, rubbing or immersion.

c. Independent Claim 24

Independent claim 24 is directed to a method for sterilizing un-sterilized poultry meat comprising: contacting the un-sterilized poultry meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water at a temperature of 0° to 70°C; at a pH of 4 to 11 (page 8, lines 17-21); at a concentration of 1 to 50000 ppm (page 7, lines 1-7); thereby producing sterilizing poultry meat. The embodiment of claim 24 is described at pages 7-12 of the specification.

d. Independent Claim 25

Independent claim 25 is directed to a method for converting live poultry into sterilized, wrapped, poultry meat comprising the steps of:

I. providing live poultry (page 9, lines 3-5); and then

II. killing and eviscerating the live poultry thereby producing an un-sterilized carcass comprising skin, dark meat, and white meat (page 9, lines 2-12); wherein the un-sterilized carcass is contaminated with unwanted microorganisms; and then

III. contacting the un-sterilized carcass and/or the meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water (page 7, lines 19-26, page 8, lines 1-16) at a concentration of 1 to 50000 ppm of hinokitiol (page 7, lines 1-7) thereby:(a) killing the unwanted microorganisms; and (b) providing a residue of hinokitiol solution on the meat; and then

IV. wrapping the carcass and/or the meat without removal of the residue of hinokitiol solution on the meat (page 12, lines 1-2); thereby producing sterilizing, wrapped, poultry meat without adversely affecting either the color or the taste of the meat (page 12, lines 9-14).

VI. Grounds of Rejection to Be Reviewed on Appeal

The rejection of the Examiner to be reviewed on appeal is the following:

Claims 11-22 and 24-27 stand finally rejected under 35 USC 103(a) as being unpatentable over Kurschner et al U.S. Patent No. 5,632,676 in view of Nishimoto et al U.S. Patent No. 6,165,964 and Takahashi U.S. Patent No. 6,352,727.

VII. Arguments

A. Issue presented for appeal

The issue presented for appeal is whether the Examiner has presented a *prima* facie case of obviousness based on the combined teachings of the Kurschner et al,

Nishimoto et al and Takahashi references and, if so, has such a *prima facie* case of obviousness been overcome by the evidence of record.

B. The Evidence of Record

Two Declarations under 37 CFR 1.132 are made of record in rebuttal of the rejection under 35 USC 103(a) as follows:

- (i) Declaration under 37 CFR 1.132 dated April 8, 2003 (which demonstrates the efficacy of the use of hinokitiol as a sterilizing agent for use with poultry meat); and
- (ii) Declaration under 37 CFR 1.132 dated September 30, 2003 (which demonstrates the efficacy of the use of hinokitiol as a sterilizing agent for use with poultry meat in relation to the use of the prior art sterilizing agent peracetic acid).

Comparative data relied by appellant also resides in the Examples and drawings of appellant's specification.

C. Argument in Support of Patentability

1. The Present Invention and Its Advantages

The control of microorganisms during poultry processing is generally difficult.

During such processing, the meat can become contaminated during transportation or at any stage of the processing. The microorganisms can originate from the air, water, ice or the processing machinery itself.

Numerous methods exist for controlling the level of microorganisms in poultry. Some methods involve the adjustment of the temperature and pH of water (see appellant's specification at page 2, lines 1-4). Other methods have been proposed but result in the use of hazardous materials such as chlorine gas, incomplete sterilization and/or environmental pollution.

By contrast, the claimed invention provides a safe, simple and effective method of sterilizing poultry meat during processing. The present invention is directed to a method of sterilizing poultry meat comprising the step of subjecting poultry meat during poultry processing to contact an aqueous solution consisting essentially of hinokitiol. The contact treatment is carried out in one or more steps, including during or between an evisceration step, a chilling step and a wrapping step. The contacting step may occur by coating, rubbing, spraying or immersing the poultry meat in the aqueous hinokitiol solution.

The claimed invention enables advantages to be achieved which have been experimentally confirmed. As can be seen from Table 1 and Figures 3-7 of the specification, and the Declarations under 37 CFR 1.132 made of record by appellant, the present invention

not only provides safe and effective sterilization in comparison to conventional methods, but such sterilization occurs without affecting the appearance of the treated meat (such as by the appearance of unsightly whitening of the meat), and without causing an irritating odor. The claimed invention is neither disclosed nor suggested by the prior art of record.

2. The Examiner Fails to Present a Prima Facie Case of Obviousness

The Examiner has the burden under 35 USC 103(a) to establish a prima facie case of obviousness. In re Fine, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988). The burden can only be established by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. In re Fine, 5 USPQ 2d at 1598. In the absence of a proper prima facie case of obviousness, an applicant who complies with the other requirements of the statute is entitled to a patent. In re Oetiker, 24 USPQ 2d 1443, 1444 (Fed. Cir. 1992). Appellant submits that the Examiner has failed to present a prima facie case of obviousness.

The Examiner rejects claims 11-22 and 24-27 under 35 USC 103 (a) as being unpatentable over Kurschner et al U.S. Patent No. 5,632,676 in view of Nishimoto et al U.S. Patent No. 6,165,964 and Takahashi U.S. Patent No. 6,352,727.

The Examiner takes the position at pages 2-3 of the Final Rejection that:

 Kurschner teaches sterilizing poultry meat with an aqueous antibacterial solution of peracetic acid while acknowledging that Kurschner is silent with regard to the use of hinokitiol as the antibacterial agent.

- Nishimoto et al to teaches the use of an aqueous solution of hinokitiol for use in food factories for purposes of disinfection.
- Takahashi teaches that hinokitiol may be used to "treat the meat itself" instead of just meat processing equipment.

The Examiner concludes at page 3 of the Action:

"Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by modifying the antibacterial solution of Kurschner et al by substituting the antibacterial solution hinokitiol as taught by Nashimoto et al to sterilize poultry meat during processing. Further, Takahashi teaches that the hinokitiol solution has a wide range of uses such as sterilizing utensils or sterilizing meat. As such, this would only be the substituting of one well known sterilizing agent for another."

The Examiner further states at page 5 of the Action regarding the relevance of the Takahashi reference:

"Applicant argues that the addition of the Takahashi reference fails to supply what is missing in the combination of Kurschner et al and Nishimoto et al '964 since Takahashi does not teach that hinokitiol solution can treat both meat and meat processing equipment. However, column 6, lines 20-29 of Takahashi teaches that there can be a mix of bactericides to treat food, and column 7, lines 4-8 of Takahashi indicates hinokitiol as one of the bactericides. Finally, column 7, lines 30-55 of Takahashi suggests how bactericides are mixed to be used on meats. As such, the Takahashi reference is the link to show that various bactericides can be used on both equipment and meat and that hinokitiol is a well known bactericide included in this grouping."

The Examiner fails to present a *prima facie* case of obviousness as the cited references, taken either singly or in combination, not only fail to teach or suggest the claimed invention, but fail to provide the requisite motivation to arrive at the claimed invention.

Kurschner is directed to a method of sanitizing eviscerated fowl by contacting the fowl with a solution of *peracetic acid* containing from 100 to 2000 ppm peracetic acid. No mention is made in Kurschner of the use of hinokitiol as a sterilizing agent. The patent teaches that the use of peracetic acid is intended to improve upon the use of hydrogen peroxide solution as a sanitizing solution as hydrogen peroxide results in undesirable side effects such as bloating, discoloration of the meat, and change in texture whereby the meat becomes either rubbery or leathery in texture (column 1, lines 40-47; column 2, lines 41-51).

Again, the Kurschner patent is, as acknowledged by the Examiner, completely silent with regard to the use of an aqueous solution "consisting essentially of hinokitiol" as a sterilizing agent, much less as a sterilizing agent for use during the processing of poultry meat.

Nishimoto is relied upon as teaching the use of an aqueous antibacterial solution of hinokitiol for purposes of disinfecting.

Nishimoto teaches that a hinokitiol solution exhibits antimicrobial properties, stating as follows:

"When the aqueous solution is used as antimicrobial agents and so forth, the solution is diluted to an extent such that an antimicrobial effect is manifested by the antimicrobial components in the solution. For example, when the Hiba oil and/or Taiwan Hinoki oil is used, the hinokitiol content is preferably in the range of at least 0.05% by weight but not larger than 0.5% by weight.

The antimicrobial agent or microbiocide of the present invention comprises the above-mentioned aqueous solution of essential oil from plants. The antimicrobial agent or microbiocide of the present invention is useful, because they exhibit broad antimicrobial spectrum to many kinds of microbes, and do not generate resistant strain to them. For example, the

antimicrobial agent and/or microbicide can be widely used for kitchen goods such as kitchen towel, a cutting board, and knives; filters for air conditioner, air cleaner and electric cleaner; and medical devices such as an inhalator, and a humidifier. Therefore, the antimicrobial agent or microbiocide of the present invention is widely used in hospitals or food factories.

The treatment of articles with the antimicrobial agent and/or microbiocide of the present invention are conducted by applying the antimicrobial agent and/or microbicide. For example, when aqueous solution containing Taiwan Hiroki oil or Hiba oil at a hinokitiol concentration of about 0.05 to 0.5% by weight is used, articles to be treated are immersed in the solution. The antimicrobial agent and/or microbiocide of the present invention may also be used for washing hands. The antimicrobial agent and/or microbiocide of the present invention show antibacterial spectrum for Staphylococcus, enteropathogenicEscherichia coli, Salmonella, and Legionella, in particular, it shows the antibacterial activities for MRSA or enteropathogenic E. coli 0-157. Therefore, the antimicrobial agent and/or microbiocide of the present invention are suitable as prophylactic or microbiocide for serious infectious disease caused by such bacteria." (column 8, line 54 to column 9, line 22)

It is clear from such teachings that the Nishimoto reference, while teaching the use of a hinokitiol-containing solution as an anti-microbial agent and/or micro-biocide, fails to teach or suggest the use of an aqueous solution consisting essentially of hinokitiol during food processing in general, or during the processing of poultry meat in particular, in the manner claimed by appellant.

The additionally-cited Takahashi reference describes a bactericide or a fungicide comprising a polar solvent extract of leaves of eucalyptus plants and chitosan. Hinokitiol.is not intended to be a basic component of the disclosed composition. Hinokitiol is merely one of a multitude of disclosed bactericides or fungicides which may be combined with the

primary composition as an ancillary component (column 6, lines 26 to 29, and column 7, lines 4 to 8 of the reference).

The Takahashi reference fails to teach or suggest the use of an aqueous solution consisting essentially of hinokitiol during poultry processing as claimed.

Instead, Takahashi discusses a variety of <u>non-poultry</u> processing uses for the disclosed sterilizing composition:

"As described above, the bactericide (and the fungicide) of the present invention can be used as:

- 1. bactericide (and a fungicide) for household articles such as tables, tablewares, chopping b oards, cooking stands, toilet seats at home or restaurants; cattle sheds, chicken houses, instruments in buildings for keeping animals; machines at abattoir facilities; skin of human or animals, egg shells of hens, quails or the like;
- 2. a bactericide (and a fungicide) for doors, knobs of doors, floors, handrail of beds, medical equipments such as instruments for operation, medical facilities at hospitals or old-age homes; fresh foods such as meat, fishes, vegetables, seeds of plants;
- 3. bactericide (and a fungicide) for affording a bactericide power to: living things such as wet tissues, diapers, sheets, clothes, sanitary cotton, wipers for hip, non-woven textiles, oil removing papers, papers (sheets) for food packing, papers (sheets) for laying under the foods, the paper mule, moist hand towels, towels, coverings, or the like; fodder for animals, fishes or the like; foods, for example, gum, candies, products made of boiled fish paste (kamaboko), tubular rolls of boiled fish paste (chikuwa) or the like, confectionaries, Japanese confectionaries, noodles such as undried noodles, buckwheat noodles (soba) or the like, seasonings such as sauce, soy sauce, or the like, pickles, delicatessen, processed foods of eggs, sandwiches, mayonnaise, cream puff or the like;
- 4. bactericide (and a fungicide) for being mixed in cosmetics such as soaps, cleaning agents or cream or added to pharmaceuticals to be orally administered." (column 30, line 42 to column 31, line 23)

None of the uses in Takahashi's above extensive listing of uses is directed to poultry processing as claimed by appellant. At best, Takahashi teaches that the disclosed

bactericide (or fungicide) may be used "for meat (including meat products such as ham, sausage or the like)." See column 3, lines 20-32 of Takahashi.

However, such a teaching has no relevance to the use of an anti-microbial agent during the processing of poultry as claimed by appellant. It should further be noted that the teachings of Takahashi are generally intended to be directed to the use of a bactericide (or fungicide) comprised primarily of a polar solvent extract of leaves of eucalyptus plants and chilosan, wherein hinokitiol (if present) is present in minor amounts. The focus of Takahashi is clearly not directed to a hinokitiol-based bactericide which consists essentially of hinokitiol as provided for in appellant's claims.

Based on the above, one of ordinary skill in the art would not be motivated to combine the respective teachings of the cited references to arrive at the claimed invention. There are three possible sources of motivation to combine references: the nature of the problem to be solved, the teaching of the prior art, and the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

Here, the requisite motivation is lacking since one of ordinary skill in the art would not refer to either Nishimoto or Takahashi in order to modify the process of Kurschner in the manner asserted by the Examiner. Nishimoto generally teaches the use of hinokitiol as a bacterial agent while being silent regarding poultry processing. Takahashi generally teaches that hinokitiol (as a minor component) may be used in conjunction with another sterilizing

agent in a variety of end uses, <u>none</u> of which involve the sterilization of poultry meat during processing.

One of ordinary skill in the art simply would not be directed by the teachings of Nishimoto and/or Takahashi to substitute an aqueous solution consisting essentially of hinokitiol for the peracetic acid solution of Kurschner in the absence of some objective teaching that such a substitution would be either prudent or rational in view of possible adverse effects upon the poultry meat so treated.

Despite the fact that Nishimoto and Takahashi may teach the use of a sterilizing agent to sterilize various goods or devices, one of ordinary skill in the art would not equate such teachings with the sterilization of food. Instead, one of ordinary skill in the art recognizes that great care is exercised when using sterilizing compositions for food to avoid compromising the edibility of the food. For example, great care must be taken by one of ordinary skill in the art to avoid adversely affecting the color and/or flavor of the food to be sterilized.

Kurschner discusses these problems faced by one of ordinary skill in the art when sterilizing food. Specifically, Kurschner refers to the bloated appearance, changes in texture, and the discoloration in poultry meat caused by various sterilization methods (see column. 1, lines 39-56). Indeed, Kurschner teaches that peracetic acid should not be used in direct contact with fowl, "perhaps because of an adverse experience with hydrogen peroxide" (column 1, lines 54-56). Thus, in view of the considerable problems involved in sterilizing food, one of ordinary skill in the art would not logically equate disinfecting compositions

used for kitchen goods, machinery, filters, for example, with compositions used for the sterilization of food.

The present invention is accordingly directed to an invention neither taught nor suggested by the cited references – the sterilizing of poultry meat comprising the step of contacting poultry meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water as shown by the following discussion of the claims on appeal:

a. Claims 11, 13-15, 26 and 27

The cited prior art fails to teach or suggest the use of an aqueous solution consisting essentially of hinokitiol in poultry processing for the processing of poultry meat comprising contacting the poultry meat with the aqueous solution during one or more evisceration, chilling or wrapping steps, with the treated poultry meat being wrapped (claim 11). Kurschner et al, the only reference directed to sterilizing poultry meat during processing, is completely silent with regard to the use of an aqueous solution consisting essentially of hinokitiol as the sterilizing agent. As discussed above, neither Nishimoto nor Takahashi provide the requisite motivation or suggestion to use such an aqueous solution in the process of Kurschner.

The prior art also fails to disclose or suggest the use of such a sterilizing agent in the amount of from 1 to 50,000 ppm (claim 13), a pH of from 4 to 11 (claim 14), a contacting temperature of from 0° to 70°C (claim 15), the presence of a surfactant (claim 26), or a plant extract (claim 27).

b. Claims 17 and 18-22

The cited prior art fails to disclose or suggest a method of sterilizing poultry meat comprising the step of subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution consisting essentially of hinokitiol and water during poultry processing for production of poultry meat, wherein the contact treatment is carried out in one or more intervals between consecutive two steps selected from the group consisting of (1) between an evisceration step and a chilling step and (2) between a chilling step and a wrapping step, wherein the hinokitiol aqueous solution-contacted poultry meat is wrapped (claim 17).

Kurschner et al, the only reference directed to sterilizing poultry meat during processing, is completely silent with regard to the use of an aqueous solution consisting essentially of hinokitiol as the sterilizing agent. Kurschner also fails to disclose or suggest the contacting of the poultry meat with the hinokitiol solution in one or more intervals between any two consecutive steps (between evisceration and chilling step, and between a chilling step and wrapping step). As discussed above, neither Nishimoto nor Takahashi provide the requisite motivation or suggestion to use such an aqueous solution in the process of Kurschner.

The prior art also fails to disclose or suggest the use of such a sterilizing agent in the amount of from 1 to 50,000 ppm (claim 19), a pH of from 4 to 11 (claim 20), or a contacting temperature of from 0° to 70°C (claim 21).

c. Independent Claim 24

The cited prior art fails to disclose or suggest a method for sterilizing un-sterilized poultry meat comprising: contacting the un-sterilized poultry meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water at a temperature of 0° to 70°C; at a pH of 4 to 11; at a concentration of 1 to 50000 ppm; thereby producing sterilizing poultry meat.

Kurschner et al, the only reference directed to sterilizing poultry meat during processing, is completely silent with regard to the use of an aqueous solution consisting essentially of hinokitiol as the sterilizing agent. Given such a deficiency, the reference also fails to teach the recited conditions of claim 24. As discussed above, neither Nishimoto nor Takahashi provide the requisite motivation or suggestion to use such an aqueous solution in the process of Kurschner.

d. Independent Claim 25

The cited prior art fails to disclose or suggest a method for converting live poultry into sterilized, wrapped, poultry meat comprising the steps of:

- I. providing live poultry; and then
- II. killing and eviscerating the live poultry thereby producing an un-sterilized carcass comprising skin, dark meat, and white meat; wherein the un-sterilized carcass is contaminated with unwanted microorganisms; and then
- III. contacting the un-sterilized carcass and/or the meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water at a concentration of 1 to 50000 ppm

of hinokitiol thereby:(a) killing the unwanted microorganisms; and (b) providing a residue of hinokitiol solution on the meat; and then

IV. wrapping the carcass and/or the meat without removal of the residue of hinokitiol solution on the meat; thereby producing sterilizing, wrapped, poultry meat without adversely affecting either the color or the taste of the meat.

Kurschner et al, the only reference directed to sterilizing poultry meat during processing, is completely silent with regard to the use of an aqueous solution consisting essentially of hinokitiol as the sterilizing agent. Given such a deficiency, the reference also fails to teach the recited conditions of claim 25. As discussed above, neither Nishimoto nor Takahashi provide the requisite motivation or suggestion to use such an aqueous solution in the process of Kurschner.

In summary, as none of the claimed embodiments are disclosed or suggested by Kurschner et al, Nishimoto et al or Takahashi, taken either singly or in combination, the advantageous effects resulting from the claimed invention can neither be predicted nor expected from the combined teachings of these references.

The Examiner thus fails to present a *prima facie* case of obviousness in support of the rejection.

3. The Evidence of Record Overcomes any Prima Facie Case of Obviousness

Even if the Honorable Board believes that a prima facie case of obviousness has been presented by the Examiner, the evidence of record overcomes any such prima facie case of obviousness.

Appellant makes of record two Declarations under 3.7 CFR 1.132 which, taken together with the comparative data in the specification, confirm the patentability of the claimed invention, and overcome any *prima facie* case of obviousness that may have been presented.

More specifically, as can be seen from Table 1 and Figures 3-7 of the specification, the present invention unexpectedly provides a safer and more effective sterilization method for poultry meat in comparison to the use of an aqueous hypochlorite solution. An aqueous solution of hinokitiol is shown to be overall more effective than hypochlorite in reducing the level of bacteria in treated chicken meat, while the aqueous solution of hinokitiol is orders of magnitude more effective with respect to certain of the treated bacteria.

In addition, the Declarations submitted by appellant demonstrate that the use of hinokitiol as a disinfectant unexpectedly does <u>not</u> adversely affect the color and/or taste of poultry meat, which result is not taught by the cited prior art.

The Honorable Board's attention is directed to the Declaration of April 8, 2003 which confirms that the treatment of chicken breast meat with an aqueous solution of hinokitiol does not affect the color of the chicken breast meat. It is also confirmed that the treatment of chicken breast meat with an aqueous solution of hinokitiol does not substantially affect the taste of the meat.

Appellant's Declaration of September 30, 2003 compares the effectiveness of the use of an aqueous solution of hinokitiol with an aqueous solution of peracetic acid (consistent with the teachings of the Kurschner reference relied upon by the Examiner). The Declaration

confirms that no adverse "whitening" of the poultry meat occurs upon being contacted with an aqueous solution of hinokitiol, and also that no irritable odor is caused to occur in the poultry meat.

It is also demonstrated therein that the contacting of poultry meat with an aqueous solution of peracetic acid results in advanced whitening of the meat after only 0.5 hour (in contrast to the results observed upon use of hinokitiol solution). The whitening effect advanced further two hours after contact with peracetic acid solution, with no such effect being observed after contact with a hinokitiol solution. The whitening effect continued to advance even after 24 hours after contact with the peracetic acid solution, which effect was not observed upon contact with the hinokitiol solution.

With regard to the odor of the treated poultry meat, no irritable odor or smell was observed in connection with the hinokitiol-treated poultry meat. On the other hand, an irritating odor became apparent upon use of the peracetic acid depending upon the concentration of peracetic acid in the treatment solution. For instance, when the concentration of the peracetic acid was as high as 1000 ppm, the irritable odor became so strong as to render the poultry meat inedible.

Appellant has thus demonstrated that an a queous solution of hinokitiol is not a functional equivalent of an aqueous solution of peracetic acid from the standpoint of treatment of poultry meat. Indeed, appellant has demonstrated that, under certain conditions, treatment of poultry meat with an aqueous solution of peracetic acid (as taught by

Kurschner) can render the poultry meat inedible, a result which is shown to <u>not</u> occur upon use with an aqueous solution of hinokitiol.

Appellant thus demonstrates that no art-recognized equivalence exists with respect to sterilizing agents for poultry meat. Indeed, the Examiner's assumption that one of ordinary skill in the art may merely substitute one sterilizing agent for another is without factual basis given the significant functional differences that have been shown to exist (and which are recognized by the prior art) between the use of various sterilizing agents with respect to the treatment of poultry meat.

The use of an aqueous solution consisting essentially of hinokitiol in the processing of poultry meat in the manner claimed accordingly yields advantages and results neither suggested nor predicted by the cited prior art. Such results clearly overcome any *prima* facie case of obviousness which the Honorable Board may believe has been established by the Examiner.

VIII. Conclusion

The Final Rejection of claims 11-22 and 24-27 is without basis and should be reversed. The Examiner fails to present a prima facie case of obviousness, and even if a prima facie case of obviousness has been presented, the comparative data of record overcomes such a prima facie case of obviousness and confirms the patentability of the claimed invention.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Falls Church,

(703) 205-8000

1422-0508P

Claims Appendix

11. A method of sterilizing poultry meat comprising the step of subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution consisting essentially of hinokitiol and water in poultry processing for a production of poultry meat, wherein the contact treatment is carried out in one or more steps selected from the group consisting of an evisceration step, a chilling step and a wrapping step

wherein the hinokitiol aqueous solution-contacted poultry meat is wrapped.

- 12. The method according to claim 11, wherein the contact treatment is further carried out in the interval between the evisceration step and the chilling step or in the interval between the chilling step and the wrapping step.
- 13. The method according to claim 11, wherein the concentration of hinokitiol in the aqueous hinokitiol solution is from 1 to 50000 ppm.
- 14. The method according to claim 11, wherein the aqueous hinokitiol solution has a pH of 4 to 11.
- 15. The method according to claim 11, wherein the contact treatment is carried out at a temperature of 0° to 70°C.

- 16. The method according to claim 11, wherein the contact treatment is carried out by at least one selected from the group consisting of applying a coat, spraying, rubbing and immersion.
 - 17. A method of sterilizing poultry meat comprising the step of

subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution consisting essentially of hinokitiol and water in poultry processing for a production of poultry meat, wherein the contact treatment is carried out in one or more intervals between consecutive two steps selected from the group consisting of: between an evisceration step and a chilling step and between a chilling step and a wrapping step

wherein the hinokitiol aqueous solution-contacted poultry meat is wrapped.

- 18. The method according to claim 17, wherein the contact treatment is further carried out at the chilling step.
- 19. The method according to claim 17, wherein the concentration of hinokitiol in the aqueous hinokitiol solution is from 1 to 50000 ppm.
- 20. The method according to claim 17, wherein the aqueous hinokitiol solution has a pH of 4 to 11.

- 21. The method according to claim 17, wherein the contact treatment is carried out at a temperature of 0° to 70°C.
- 22. The method according to claim 17, wherein the contact treatment is carried out by at least one selected from the group consisting of applying a coat, spraying, rubbing and immersion.
 - 24. A method for sterilizing un-sterilized poultry meat comprising:

contacting the un-sterilized poultry meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water at a temperature of 0° to 70°C; at a pH of 4 to 11; at a concentration of 1 to 50000 ppm; thereby producing sterilizing poultry meat.

- 25. A method for converting live poultry into sterilizing, wrapped, poultry meat comprising the steps of:
 - I. providing live poultry; and then
- II. killing and eviscerating the live poultry thereby producing an un-sterilized carcass comprising skin, dark meat, and white meat; wherein the un-sterilized carcass is contaminated with unwanted microorganisms; and then
- III. contacting the un-sterilized carcass and/or the meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water at a concentration of 1 to 50000 ppm of hinokitiol thereby:

- (a) killing the unwanted microorganisms; and
- (b) providing a residue of hinokitiol solution on the meat; and then
- IV. wrapping the carcass and/or the meat without removal of the residue of hinokitiol solution on the meat;

thereby producing sterilizing, wrapped, poultry meat without adversely affecting either the color or the taste of the meat.

- 26. The method according to claim 11, wherein said aqueous hinokitiol solution further contains a surfactant safe for human consumption.
- 27. The method according to claim 11, wherein said aqueous hinokitiol solution further contains a plant extract.

Evidence Appendix

The attached Declarations under 37 CFR 1.132 were made of record during examination:

- (1) Declaration under 37 CFR 1.132 dated April 8, 2003 (filed with response dated May 6, 2003);
- (2) Declaration under 37 CFR 1.132 dated September 30, 2003 (filed with responses dated October 2 and 16, 2003).

Related Appeals and Interferences Appendix

No related appeals or interferences exist.